PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application No.:	10/601,952	Confirmation No.: 7910
Applicant :	Karl A. Jagger et al.	
Filed :	June 23, 2003	
TC/A.U. :	3731	
Examiner :	Sonnett, Kathleen C.	
Title:	ASYMMETRIC STENT DELIVERY SYSTEM WITH PROXIMAL EDGE PROTECTION AND METHOD OF MANUFACTURE THEREOF	
Docket No. :	1001.2192101	
Customer No. :	28075	

APPEAL BRIEF FILED UNDER 37 C.F.R. § 41.37

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By _____
JoAnn Lindman

Dear Sir:

Pursuant to 37 C.F.R. § 41.37, Appellant hereby submits this Appeal Brief in furtherance of the Notice of Appeal filed on April 19, 2010, and of the Notice of Panel Decision from Pre-Appeal Review dated Mailed June 21, 2010. Appellant authorizes the fee prescribed by 37 C.F.R. § 41.20(b)(2) in the amount of $540.00 to be charged to Deposit Account No. 50-0413. Permission is hereby granted to charge or credit Deposit Account No. 50-0413 for any errors in fee calculation.

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I. REAL PARTY IN INTEREST

The real party in interest is the assignee of record, SciMed Life Systems, Inc., a corporation organized and existing under and by virtue of the laws of Minnesota, and having a business address of One SciMed Place, Maple Grove, MN 55311-1566. An assignment from the inventors, Karl A Jagger, Linda S Christenson, Todd Rowe, Stanley Nordin, Daniel Nygaard, Randall J Beyreis and Jon Livinston, conveying all right, title and interest in the invention to SciMed Life Systems, Inc. has been recorded at Reel 014676, Frame 0042. A name change from SciMed Life Systems, Inc. to Boston Scientific Scimed, Inc. has been recorded at Reel 018505, Fram 0868.

II. RELATED APPEALS AND INTERFERENCES

There are no other known appeals or interferences that will directly affect, or be directly affected by, or have a bearing on the Board's decision in this appeal.

III. STATUS OF CLAIMS

Claims 1-30 are pending in the application, of which, claims 1-8 and 21-30 are withdrawn.

Claims 9 and 13 stand finally rejected under 35 U.S.C. §103(a) as being unpatentable over Shortt (U.S. Patent No. 6,948,223) in view of Morales (U.S. Patent No. 5,920,975) and Hanson et al. (U.S. Patent No. 5,893,868).

Claim 12 stands finally rejected under 35 U.S.C. §103(a) as being unpatentable over Shortt (U.S. Patent No. 6,948,223) in view of Morales (U.S. Patent No. 5,920,975) and Hanson et al. (U.S. Patent No. 5,893,868), as applied to claim 9 above, and further in view of Euteneuer et al. (U.S. Patent No. 5,147,302).

Claims 9 and 18 stand finally rejected under 35 U.S.C. §103(a) as being unpatentable over Shortt (U.S. Patent No. 6,948,223) in view of Morales (U.S. Patent No. 5,920,975) and Hanson et al. (U.S. Patent No. 5,893,868).

Claims 10 and 11 stand finally rejected under 35 U.S.C. §103(a) as being unpatentable over Shortt (U.S. Patent No. 6,948,223) in view of Morales (U.S. Patent No. 5,920,975) and

Hanson et al. (U.S. Patent No. 5,893,868), as applied to claim 9 above, and further in view of Miraki et al. (U.S. Patent No. 5,704,845).

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Claims 14 and 15 stand finally rejected under 35 U.S.C. §103(a) as being unpatentable over Shortt (U.S. Patent No. 6,948,223) in view of Morales (U.S. Patent No. 5,920,975) and Hanson et al. (U.S. Patent No. 5,893,868), as applied to claim 9 above, and further in view of Motsenbocker et al. (U.S. Patent No. 6,629,350).

Claims 16-17 and 19-20 were rejected under 35 U.S.C. §103(a) as being unpatentable over Shortt (U.S. Patent No. 6,948,223) in view of Morales (U.S. Patent No. 5,920,975) and Hanson et al. (U.S. Patent No. 5,893,868), as applied to claim 9 above, and further in view of Jendersee et al. (U.S. Patent No. 5,836,965).

Claims 9-20 of the application are currently being appealed

IV. STATUS OF AMENDMENTS

No amendments subsequent to the last Final Office Action, that of November 19, 2009, have been introduced.

V. SUMMARY OF CLAIMED SUBJECT MATTER*

The invention relates generally to a method for fabricating a balloon catheter stent deployment system wherein a balloon catheter is provided and a tubular stent is crimped onto a distal portion of the balloon with a distal end of the stent in close proximity to a point where the distal end of the balloon is attached to the inner tube of the catheter. The fabrication method allows the proximal section of the balloon to be inflated after the stent is crimped onto the distal section of the balloon. See abstract.

* The references to the specification and drawings provided herein are exemplary, and are not deemed to be limiting.

Turning now to independent claim 9, which is directed to a method for fabricating a balloon catheter stent deployment system, the method comprising providing a balloon catheter (Fig. 1, numeral 10; page 6, line 16) comprising an inner tubular shaft (Fig. 1, numeral 12; page 6, line 17) disposed within an outer tubular shaft (Fig. 1, numeral 13; page 6, line 18), the inner and outer shafts each having proximal and distal ends (Fig. 1, numeral 14, 15; page 6, lines 18-19), the distal end (Fig. 1, numeral 14; page 6, line 18) of the inner shaft (Fig. 1, numeral 12; page 6, line 17) extending distally beyond the distal end (Fig. 1, numeral 15; page 6, line 19) of the outer shaft (Fig. 1, numeral 13; page 6, line 18), and an inflatable balloon (Fig. 1, numeral 16; page 6, line 20) having a proximal end (Fig. 1, numeral 17; page 6, line 21) attached to the outer shaft (Fig. 1, numeral 13; page 6, line 18) near the distal end (Fig. 1, numeral 15; page 6, line 19) thereof and a distal end (Fig. 1, numeral 18; page 6, line 23) attached to the inner shaft shaft (Fig. 1, numeral 12; page 6, line 17) near the distal end thereof (Fig. 1, numeral 14; page 6, line 18); placing a stent (Fig. 2, numeral 25; page 6, line 31-31) over the balloon (Fig. 2, numeral 16; page 6, line 30-31) so that a distal end (Fig. 2, numeral 26; page 6, line 32-33) of the stent (Fig. 2, numeral 25; page 6, line 31) is disposed proximally to the distal end (Fig. 2, numeral 18; page 6, line 32-33) of the balloon (Fig. 2, numeral 16; page 6, line 30-31) leaving a distal section (Fig. 2, numeral 24; page 6, line 32-33) of the balloon (Fig. 2, numeral 16; page 6, line 30-31) extending from the distal end (Fig. 2, numeral 26; page 6, line 32-33) of the stent (Fig. 2, numeral 25; page 6, line 31-32) to the distal end (Fig. 2, numeral 18; page 6, line 32-33) of the balloon (Fig. 2, numeral 16; page 6, line 30-31) uncovered by the stent (Fig. 2, numeral 25; page 6, line 31-32), crimping the stent (Fig. 3, numeral 25; page 7 line 7-8) onto the balloon (Fig. 3, numeral 16; page 7 line 7-8) to leave the stent with an initial outer diameter, placing a stepped enclosure (Fig. 4, numeral 40; page 7, line 17-19) over the stent and balloon wherein the stepped enclosure comprising a first section (Fig. 4, numeral 41; page 7, line 20) having a first inner diameter and that is connected to a second section (Fig. 4, numeral 42; page 7, line 20) having a second inner diameter, the first inner diameter being greater than the second inner diameter (page 7, line 20), the second inner diameter being greater than the initial outer diameter of the stent but in close approximation thereto (page 8, lines 5-7), the second section of the stepped enclosure being longer than the stent (page 7, lines 25-29), and wherein the first section of the stepped

enclosure is disposed over the proximal section (Fig. 4, numeral 23; page 7, line 22-23) of the balloon (page 8, lines 22-23) and the second section of the stepped enclosure is disposed over the stent and the distal section (Fig. 4, numeral 24; page 7, line 22-25) of the balloon uncovered by the stent (page 7, lines 22-25), inflating the balloon (Fig. 5, numeral 16; page 8, line 1) so that the proximal section (Fig. 5, numeral 23, page 8, line 2) of the balloon inflates and engages the first section (Fig. 5, numeral 41; page 8, line 3) of the stepped enclosure and the stent and a portion of the balloon disposed beneath the stent and the distal section of the balloon uncovered by the stent are prevented from substantial expansion by the second section of the stepped enclosure (page 8, lines 3-4), and the maximum outer diameter of the distal section of the balloon uncovered by the stent is no greater than the initial outer diameter of the stent (page 8, lines 5-9), removing the balloon and stent from the stepped enclosure (page 9, lines 14-15).

Claim 11 depends from claim 9 and further comprises inserting a protective sleeve (Fig. 1, numeral 11; page 6, lines 16-17) over the balloon catheter to a position proximal to the stent and balloon before placing the stent over the balloon, and sliding the protective sleeve over the stent after removing the stepped tube (page 9, lines 14-16).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

1. Whether claim 9 is patentable under 35 U.S.C. §103(a) as being over Shortt (U.S. Patent No. 6,948,223) in view of Morales (U.S. Patent No. 5,920,975) and Hanson et al. (U.S. Patent No. 5,893,868)?

2. Whether claims 13 and 18 are patentable under 35 U.S.C. §103(a) as being over Shortt (U.S. Patent No. 6,948,223) in view of Morales (U.S. Patent No. 5,920,975) and Hanson et al. (U.S. Patent No. 5,893,868); whether claim 12 is patentable under 35 U.S.C. §103(a) over Shortt (U.S. Patent No. 6,948,223) in view of Morales (U.S. Patent No. 5,920,975) and Hanson et al. (U.S. Patent No. 5,893,868), as applied to claim 9 above, and further in view of Euteneuer et al. (U.S. Patent No. 5,147,302); whether claims 10 and 11 are patentable under 35 U.S.C. §103(a) as over Shortt (U.S. Patent No. 6,948,223) in view of Morales (U.S. Patent No. 5,920,975) and Hanson et al. (U.S. Patent No. 5,893,868), as applied to claim 9 above, and further in view of Miraki et al. (U.S. Patent No. 5,704,845); whether claim 12 is patentable under

35 U.S.C. §103(a) over Shortt (U.S. Patent No. 6,948,223) in view of Morales (U.S. Patent No. 5,920,975) and Hanson et al. (U.S. Patent No. 5,893,868), as applied to claim 9 above, and further in view of Johnson (WO 02/066095); whether claims 14 and 15 are patentable under 35 U.S.C. §103(a) over Shortt (U.S. Patent No. 6,948,223) in view of Morales (U.S. Patent No. 5,920,975) and Hanson et al. (U.S. Patent No. 5,893,868), as applied to claim 9 above, and further in view of Motsenbocker et al. (U.S. Patent No. 6,629,350); and whether claims 16-17 and 19-20 are patentable under 35 U.S.C. §103(a) over Shortt (U.S. Patent No. 6,948,223) in view of Morales (U.S. Patent No. 5,920,975) and Hanson et al. (U.S. Patent No. 5,893,868), as applied to claim 9 above, and further in view of Jendersee et al. (U.S. Patent No. 5,836,965)?

3. Whether claim 11 is patentable under 35 U.S.C. §103(a) over Shortt (U.S. Patent No. 6,948,223) in view of Morales (U.S. Patent No. 5,920,975) and Hanson et al. (U.S. Patent No. 5,893,868), as applied to claim 9 above, and further in view of Miraki et al. (U.S. Patent No. 5,704,845)?

VII. ARGUMENT

A. CLAIM 9 IS PATENTABLE UNDER 35 U.S.C. §103(A) OVER SHORTT (U.S. PATENT NO. 6,948,223) IN VIEW OF MORALES (U.S. PATENT NO. 5,920,975) AND HANSON ET AL. (U.S. PATENT NO. 5,893,868).

1. All words in a claim must be considered in judging the patentability of that claim against the prior art.

"All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). The Final Office Action characterizes Shortt as disclosing a method for fabricating a balloon catheter stent deployment system comprising "providing a balloon catheter with an inner tubular shaft disposed within an outer tubular shaft, the distal end of the inner shaft extending distally beyond the distal end of the outer shaft, and an inflatable balloon having a proximal end attached to the outer shaft

near the distal end thereof and a distal end attached to the inner shaft near the distal end thereof (see Fig. 2)". Appellants respectfully disagree. Fig. 2, reproduced below for convenience, discloses a catheter assembly comprising an inner tube and an outer tube joined co-terminally at their respective distal ends, illustrated within the section labeled "4th TFE". There is no separate balloon element and thus no attachments between the distal and proximal respective ends of a balloon element and the (distally co-terminal) distal ends of the inner and outer tubes.

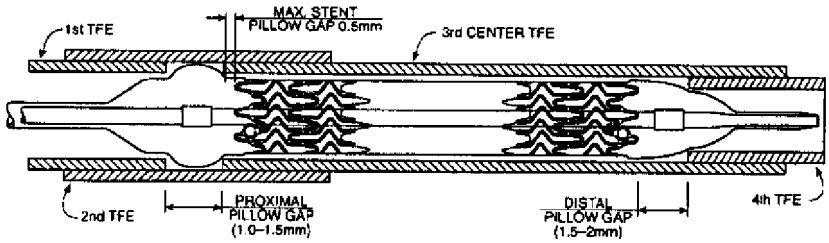

FIG._2 (PRIOR ART)

With respect to the order of the steps of crimping the stent and placing the stent over the balloon, Shortt specifies that step of crimping is done prior to the stent being placed over the balloon (col. 2, lines 54-55), but is not yet crimped to fix the position of the stent relative to the balloon catheter assembly. Instead, the Shortt specifies that stent may be positioned on the balloon between the markers. Were the stent to be crimped directly to the balloon as suggested by the proposed combination of Shortt and Morales, the stent would not be positionable between the markers after crimping as taught by Shortt. One of ordinary skill in the art would not be motivated to give up this positionability by making the modification proposed to prevent the stent from sliding off of the catheter when the catheter is advanced because the stent delivery system of Shortt already has an adequate means of retaining the stent relative to the delivery system. As depicted in Fig. 2, there appears to be no significant risk that the stent would be dislodged from the catheter of Shortt during translation.

With respect to the maximum outer diameter of the distal section of the balloon of Shortt, it will be seen in the cited Fig. 2, reproduced above, that the diameter of the distal section of the balloon formed by the prior art disclosed by Shortt, and also in the embodiment produced by the method of Shortt, is larger than the outer diameter of the stent of Shortt, especially since the "initial diameter" of the stent, as recited in pending claim 9 is that of the crimped stent of the unidentified prior art reference of Shortt. Modification by pre-crimping the stent as taught by

Morales does not appear to alter the expected enlargement of those portions of the balloon distal of the crimped stent upon inflation and heat setting.

Further, the Final Office Action refers to Figures 15 and 16 of Hanson with the unsupported assertion that Hanson discloses that it is well known to include only a proximal balloon pillow. The absence of a distal pillow is said to be supported by the difference between Figs. 15 and 16 and Figs. 17 and 18 which include explicit provision for forming an enlarged region in the vicinity of distal dam 20; however the processes disclosed by Shortt explicitly inflate the balloon portions of the outer tube which would create distal pillows in the region distal to end 34 of split inner sleeve 28 and outer sleeve 40 were those sleeves to be employed contrary to the disclosure of Shortt. Otherwise, the inflation and heat setting operations taught by Shortt would continue to produce proximal and distal enlarged portions having a maximum outer diameter greater than the initial outer diameter of the stent as recited in claim 9. It appears that the Final Office Action is proposing a combination of isolated features of references which might, under some circumstances, be capable of reproducing Appellants' invention without providing proper motivation for either the selection or the combination of those elements. This "reasoning" is reflected in the Advisory Action which states:

> "However, it is the examiner's position that, in view of the teachings of Hanson that no distal dam (pillow) is necessary, one skilled in the art would have found it obvious to modify the stepped enclosure of Shortt so that no distal dam (pillow) is formed since the stepped enclosure is responsible for forming the dams (pillows)"

Additionally, the Final Office Action, in the Response to Arguments, incorrectly substitutes a definition of the adverb "near" for the adjectival definition and then incorrectly parses the incorrect definition of "near" provided by dictionary.com. That definition, the second adverbial definition provided by that source, "at, within, or to a short distance" comprises a series of modifiers for the phrase "short distance" and thus in common English usage indicates "at a short distance"; "within a short distance"; or "to a short distance". The first adjectival definition provided by dictionary.com is: "being close by; not distant" and thus the common adjectival definition of "near" is understood to distinguish from "at" by consistently indicating

the presence of a relatively small separation. In this context, the distinction is relevant because claim 9 recites points of connection between the balloon and the inner and outer shafts which are near their respective distal ends. The disclosure of Shortt does not include a separate balloon attached to an inner and an outer shaft, but rather discloses a two part catheter assembly comprising an inner shaft connected at its distal end to the distal end of a second shaft. A distal portion of said second shaft will become the balloon portion of the stent catheter following heating and expansion within the mold of Shortt. Thus prior art Fig. 2 of Shortt discloses first and second tubes joined at their respective distal ends and does not disclose a balloon joined to an outer shaft and more particularly does not disclose "an inner tubular shaft disposed within an outer tubular shaft ... and an inflatable balloon having a proximal end attached to the outer shaft near the distal end thereof and a distal end attached to the inner shaft near the distal end thereof", as recited in independent claim 9 for at least the reasons that there is no separate balloon to be joined to the outer tube "near" the distal end of the outer tube and that the portion of the outer tube which eventually becomes the balloon is joined co-terminally with the inner tube rather than "near" the proximal end of the balloon. The distal end of the outer tube is joined at the distal end of the inner tube and distal of the distal end of the eventual balloon portion of the outer tube.

2. *There must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings.*

To establish *prima facie* obviousness of a claimed invention, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. *In re Kahn*, 441 F.3d 977, 986, 78 USPQ2d 1329, 1335 (Fed. Cir. 2006). The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990).

Shortt explicitly characterizes the method of the unidentified prior art as forming a distal pillow and further relies upon the formation of proximal and distal pillows to reduce the risk of relative movement between the balloon and the stent. (Col. 2, lines 4-10.) Removing the distal pillow would further impermissibly alter the operating principle of Shortt (MPEP 2143.01, VI.) Further, the Advisory Action incorrectly equates the pillows in balloon 20 produced by the heat set step of Hanson with the dams 18 and 20 which form a portion of shaft 13 of catheter 20 about which the balloon is molded. Thus it is not the stepped external enclosure of Hanson, but rather the internal dams which are responsible for the formation of the pillows in the process steps of Hanson which does not employ inflation. Again, neither the Final Office Action nor the Advisory Action does not provide a motivation for the combination of references other than replicating the invention of claim 9 and ignores the teachings of the references to do so.

3. Conclusion.

Because the combination of Shortt, Morales and Hanson does not teach all the limitations of the claimed invention and/or because there is no motivation to combine the teachings of Shortt, Morales and Hanson, the Examiner has failed to establish a *prima facie* case of obviousness. As such, claim 9 is believed to be allowable over the cited art.

B. CLAIMS 13 AND 18 ARE PATENTABLE UNDER 35 U.S.C. §103(A) OVER SHORTT (U.S. PATENT NO. 6,948,223) IN VIEW OF MORALES (U.S. PATENT NO. 5,920,975) AND HANSON ET AL. (U.S. PATENT NO. 5,893,868); CLAIM 12 IS PATENTABLE UNDER 35 U.S.C. §103(A) OVER SHORTT (U.S. PATENT NO. 6,948,223) IN VIEW OF MORALES (U.S. PATENT NO. 5,920,975) AND HANSON ET AL. (U.S. PATENT NO. 5,893,868), AS APPLIED TO CLAIM 9 ABOVE, AND FURTHER IN VIEW OF EUTENEUER ET AL. (U.S. PATENT NO. 5,147,302); CLAIMS 10 AND 11 ARE PATENTABLE UNDER 35 U.S.C. §103(A) AS OVER SHORTT (U.S. PATENT NO. 6,948,223) IN VIEW OF MORALES (U.S. PATENT NO. 5,920,975) AND HANSON ET AL. (U.S. PATENT NO. 5,893,868), AS APPLIED TO

CLAIM 9 ABOVE, AND FURTHER IN VIEW OF MIRAKI ET AL. (U.S. PATENT NO. 5,704,845); CLAIM 12 IS PATENTABLE UNDER 35 U.S.C. §103(A) OVER SHORTT (U.S. PATENT NO. 6,948,223) IN VIEW OF MORALES (U.S. PATENT NO. 5,920,975) AND HANSON ET AL. (U.S. PATENT NO. 5,893,868), AS APPLIED TO CLAIM 9 ABOVE, AND FURTHER IN VIEW OF JOHNSON (WO 02/066095); CLAIMS 14 AND 15 ARE PATENTABLE UNDER 35 U.S.C. §103(A) OVER SHORTT (U.S. PATENT NO. 6,948,223) IN VIEW OF MORALES (U.S. PATENT NO. 5,920,975) AND HANSON ET AL. (U.S. PATENT NO. 5,893,868), AS APPLIED TO CLAIM 9 ABOVE, AND FURTHER IN VIEW OF MOTSENBOCKER ET AL. (U.S. PATENT NO. 6,629,350); AND CLAIMS 16-17 AND 19-20 ARE PATENTABLE UNDER 35 U.S.C. §103(A) OVER SHORTT (U.S. PATENT NO. 6,948,223) IN VIEW OF MORALES (U.S. PATENT NO. 5,920,975) AND HANSON ET AL. (U.S. PATENT NO. 5,893,868), AS APPLIED TO CLAIM 9 ABOVE, AND FURTHER IN VIEW OF JENDERSEE ET AL. (U.S. PATENT NO. 5,836,965).

If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). As noted above, appellants believe claim 9 to be allowable over the cited art. Therefore, because claims 10-20 depend from claim 9 and include significant additional limitations, they are believed to be allowable over the cited references as well.

C. CLAIM 11 IS PATENTABLE UNDER 35 U.S.C. §103(A) OVER SHORTT (U.S. PATENT NO. 6,948,223) IN VIEW OF MORALES (U.S. PATENT NO. 5,920,975) AND HANSON ET AL. (U.S. PATENT NO. 5,893,868), AS APPLIED TO CLAIM 9 ABOVE, AND FURTHER IN VIEW OF MIRAKI ET AL. (U.S. PATENT NO. 5,704,845.

1. All words in a claim must be considered in judging the patentability of that claim against the prior art and/or there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings.

"All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). To establish *prima facie* obviousness of a claimed invention, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. *In re Kahn*, 441 F.3d 977, 986, 78 USPQ2d 1329, 1335 (Fed. Cir. 2006).

On page 7 of the Final Office Action, the Examiner writes that "Miraki et al. does not diclose keeping the protective sleeve in a proximal position to the balloon prior to and during the manufacturing step and then sliding it over the balloon after the step is completed. However, applicant has not disclosed that keeping the sleeve pre-mounted on the catheter proximal to the stent and then sliding the sleeve over the stent after removing the stepped tube is used for any particular purpose or provides any advantage. Furthermore one of ordinary skill in the art would expect the modified method of Shortt and the applicant's claimed method to perform equally well using either a protective sleeve that is pre-mounted proximally of the stent and then slid over the stent or a protective sleeve that is slide [sic] over the stent from the distal end of the stent." Contrariwise, there is an advantage to the method of claim 11. Pre-loading the protective sleeve and then sliding the protective sleeve over the stent moves the protective sleeve in a distal direction over the proximal balloon material and the stent. This causes the proximal balloon material to be deposited against the proximal edge of the stent, which provides a co-axial centering benefit to the stent delivery system upon pullback into a guide catheter at abrupt take-off angles. Without recognizing this benefit to the method of claim 11, there is no reason to modify the prior art references to include this additional step.

2. Conclusion.

Because the combination of Shortt, Morales, Hanson and Miraki does not teach all the limitations of the claimed invention and/or because there is no motivation to combine the teachings of Shortt, Morales, Hanson and Miraki, the Examiner has failed to establish a *prima facie* case of obviousness. As such, claim 9 is believed to be allowable over the cited art.

D. CONCLUSION.

For the reasons stated above, the claims 9-20 are nonobvious over the cited art, and the Examiner's rejections of claims 9-20 under 35 U.S.C. § 103(a) should be overruled.

Respectfully submitted,

Date: July 30, 2010

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VIII. CLAIMS APPENDIX

9. A method for fabricating a balloon catheter stent deployment system, the method comprising:

providing a balloon catheter comprising

an inner tubular shaft disposed within an outer tubular shaft, the inner and outer shafts each having proximal and distal ends, the distal end of the inner shaft extending distally beyond the distal end of the outer shaft, and

an inflatable balloon having a proximal end attached to the outer shaft near the distal end thereof and a distal end attached to the inner shaft near the distal end thereof;

placing a stent over the balloon so that a distal end of the stent is disposed proximally to the distal end of the balloon leaving a distal section of the balloon extending from the distal end of the stent to the distal end of the balloon uncovered by the stent,

crimping the stent onto the balloon to leave the stent with an initial outer diameter,

placing a stepped enclosure over the stent and balloon wherein the stepped enclosure comprising a first section having a first inner diameter and that is connected to a second section having a second inner diameter, the first inner diameter being greater than the second inner diameter, the second inner diameter being greater than the initial outer diameter of the stent but in close approximation thereto, the second section of the stepped enclosure being longer than the stent, and wherein the first section of the stepped enclosure is disposed over the proximal section of the balloon and the second section of the stepped enclosure is disposed over the stent and the distal section of the balloon uncovered by the stent,

inflating the balloon so that the proximal section of the balloon inflates and engages the first section of the stepped enclosure and the stent and a portion of the balloon disposed beneath the stent and the distal section of the balloon uncovered by the stent are prevented from substantial expansion by the second section of the stepped enclosure, and the maximum outer diameter of the distal section of the balloon uncovered by the stent is no greater than the initial outer diameter of the stent,

removing the balloon and stent from the stepped enclosure.

10. The method of claim 9 further comprising:

inserting a protective sleeve over the stent after removing the balloon and stent from the stepped enclosure.

11. The method of claim 9 further comprising:

inserting a protective sleeve over the balloon catheter to a position proximal to the stent and balloon before placing the stent over the balloon, and sliding the protective sleeve over the stent after removing the stepped tube.

12. The method of claim 9 wherein the first section of the stepped enclosure comprises a flared proximal end and the second section of the stepped enclosure comprises a flared distal end.

13. The method of claim 9 wherein the stepped enclosure is a stepped tube and the second section of the stepped tube extends into the first section of the stepped tube to provide an overlap section between the first and second sections.

14. The method of claim 9 wherein the stepped enclosure is formed by a plurality of crimping elements each having a stepped leading edge to form the stepped enclosure and wherein the plurality of crimping elements are movable between crimping and retracted positions.

15. The method of claim 14 wherein the plurality of crimping elements comprise part of a crimping device capable of heating the stent and balloon during the crimping of the stent onto the balloon.

16. The method of claim 9 wherein the crimping further comprises heating the stent and balloon to a temperature ranging from about 50 to about 85 °C.

17. The method of claim 9 wherein the crimping further comprises heating the stent and balloon to a temperature of about 65 °C.

18. The method of claim 9 wherein the inflating further comprises inflating the balloon with a gas having a temperature ranging from about 40 to about 60 °C.

19. The method of claim 9 wherein the inflating further comprises pressurizing the balloon to an internal pressure ranging from about 30 to about 75 psi for a time period ranging from about 5 seconds to about 1 minute.

20. The method of claim 9 wherein the inflating further comprises inflating the balloon with a gas having a temperature ranging from about 40 to about 60 °C and pressurizing the balloon to an internal pressure ranging from about 30 to about 75 psi for a time period ranging from about 5 seconds to about 1 minute.

IX. EVIDENCE APPENDIX

No additional evidence has been presented.

X. RELATED PROCEEDINGS APPENDIX

None